

DETAILED OFFICE ACTION

Applicant's amendment filed on 24 July 2009 is acknowledged and entered. Following the amendment, claims 8 and 29 are canceled, claims 4-7, 9-28, 30-34 and 37-41 are amended, and the new claims 44 and 45 are added.

Currently, claims 1-7, 9-28 and 30-45 are pending, and claims 4-7, 9-15, 27, 28, 30, 37, 44 and 45 are under consideration to the extent that they read on the elected species (an IL-15 agonist). Claims 1-3, 16-26, 31-36 and 38-43 remain withdrawn from further consideration as being drawn to a non-elected invention/species.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 8 and 29 are moot as the applicant has canceled the claims.

The scope of enablement rejection of claims 4-7 under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's amendment.

Formal Matters:

Claims

Claims 11, 13 and 15 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 10, 12 and 14. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 27, 28 and 30 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. Claim 27 depends from claim 4, wherein claim 4 requires that the IL-15 mutein comprises the full sequence of IL-15 (with one amino acid substitution). However,

Art Unit: 1646

the fragment of the dependent claim 27 does not require the same, and it only requires comprising a small portion (12 amino acids) of IL-15. Thus, claim 27 does not include every limitation of the parent claim, and does not properly further limit claim 4. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Note, a rejection under 35 U.S.C. 112, first paragraph, could be warranted if claim 27 is rewritten in independent form, and only recites the structural limitation as that in the current claim (a small portion of IL-15, i.e., the mutated region).

Claims 10 and 37 are objected to for the following informalities, and appropriate correction is required for each item:

Claim 10 recites "residue 45 by D or B" in line 2, however, "B" is not a known symbol representing any amino acid.

Claim 37 recites "*Drug* which ..." in line 1. "A pharmaceutical composition which ..." is suggested.

Rejections under 35 U.S.C. §112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite for the recitation "derivable from" because it is unclear what it is meant, and is it derived directly from the wild-type IL-15?

Claim 6 is indefinite for the recitation "at least one" since the independent claim 4 or 5, from which claim 6 is dependent, recites "*one* substitution". The claim is further indefinite for the recitation "*one hydrophobic side chain* selected from L, V and I, or of one *non-charged polar side chain* selected from S, N, and Q by a *charged group* selected from D, E, K, and R" because it is unclear what it is meant. It seems it intended to indicate amino acid substitutions. If so, the simple use of amino acid symbols is suggested.

Art Unit: 1646

Claim 7 is similarly indefinite for the recitation “one charged polar side chain” and “charged group”.

The remaining claim is included in this rejection because they are dependent from the specifically mentioned claims without resolving the indefiniteness issue belonging thereto.

Conclusion:

No claim is allowed.

Claims 9, 44 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1646

Advisory Information:

Any inquiry concerning this communication should be directed to Examiner Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dong Jiang/
Primary Examiner, Art Unit 1646
12/18/09